

### **Remarks**

The Applicants note with appreciation the removal of the objection to the specification and drawings, as well as the rejection of Claims 1-3, 5-10, 13-17 and 24-28 under 35 U.S.C. §112, second paragraph.

Claims 4 and 23 remain rejected under 35 U.S.C. §112, second paragraph. The Applicants note with appreciation the Examiner's helpful comments and have accordingly amended Claims 4 and 23 so that BRIJ has been removed in favor of polyoxyethyleneglycol dodecyl ether. The Applicants respectfully request that the change be entered into the official file. It does not raise any new issues and does not require any further search. The changes to Claims 4 and 23 are made directly in response to the Examiner's suggested language and remove an issue for potential appeal. Thus, entry into the official file is respectfully requested. Withdrawal of the rejection is also respectfully requested.

Claim 1 has also been amended to place it into better condition for allowance by improving its readability. In particular, the subject matter of paragraphs (d) and (e) has merely been reversed inasmuch as the step originally set forth in paragraph (e) follows step (a) or (c). Therefore, having the subject matter of paragraph (e) preceding paragraph (d) is merely logical. Entry into the official file is also respectfully requested.

Claims 1-5, 8, 10, 14-16 and 23-28 stand rejected under 35 U.S.C. §103 over the hypothetical combination of Schrenk with Doshi. The Applicants note with appreciation the Examiner's helpful comments hypothetically applying the combination to those rejected claims. The Applicants nonetheless respectfully submit that even if one skilled in the art made the hypothetical combination, the resulting methodology would still be quite different from the subject matter recited in those rejected claims. Details follow.

The Applicants first note with appreciation the Examiner's frank acknowledgement that Doshi does not teach selectively lysing residual cells of the filtrate. The Applicants agree. However, Doshi has a number of other serious problems that, even when combined with Schrenk, do not result in the claimed subject matter.

To begin, the Applicants specifically recite a step (a) of subjecting a sample of a blood product to an aggregation treatment of the blood cells and, separately, recite a step (b) of substantially eliminating aggregates formed in step (a) by passage of the samples over a first filter allowing passage of contaminating microbes, but not cell aggregates. The Applicants respectfully submit that Doshi does not do this. Instead, Doshi provides a filter that is impregnated with an aggregation agent. What this means is that the aggregation agent is impregnated into the filter. Thus, aggregation, to the extent that it occurs, happens as the material is already in contact with the filter and passing through the filter.

This is sharply contrasted to what Applicants' Claim 1 recites which first subjects a sample of blood product to an aggregation treatment. Then, subsequent to the aggregation treatment, the Applicants substantially eliminate the aggregates by passage of the sample over a first filter. Thus, the Applicants respectfully submit that in its most fundamental way, Doshi is quite different from what the Applicants claim. Hypothetically combining Schrenk with Doshi will not cure this difference. Thus, on this basis alone, the Applicants respectfully submit that the methodology of the combined Schrenk/Doshi disclosure is still quite different from the Applicants' language recited in Claim 1.

However, there is more. The Applicants also specifically recite recovering contaminated microbes over a second filter. Then, the Applicants analyze material on the second filter to detect labeled contaminating microbes potentially retained on the second filter. Doshi does not do this.

Instead, Doshi takes a completely different approach and Doshi analyzes what passes through the filter, not what remains behind and on the filter.

In that regard, the Applicants note with appreciation the Examiner's particular comments with respect to the second filtering step which relates to the pore sizes in Col. 12, lines 1-11 and the reactant pad through which fluid flows to allow for the production of a detectable signal at Col. 14, lines 39-41. Also, the Applicants appreciate the notation of the analyte reacting with agents to produce a detectable signal as referred to in Col. 14, lines 42-43 and that the pad may be impregnated with an appropriate enzyme or enzymes to produce a product that is measured at Col. 15, lines 10-13.

The problem with all of this disclosure is that it is quite different from what the Applicants claim in Claim 1 which specifically recites recovering contaminated microbes by passage of the lysate over a second filter and analyzing material on the second filter to detect labeled contaminating microbes possibly retained on the second filter. Thus, while the reactant pad of Doshi may provide a reagent as noted in Col. 14, lines 42-43, that reagent reacts with the material passing through the second filter, not the contaminating microbes located on the second filter. Therefore, the Applicants respectfully submit that Doshi teaches analyzing material that is completely different from what the Applicants analyze. In that regard, it should be noted that the Applicants seek to capture microbes/microbial DNA, not to pass them through the filter. Also, the Applicants analyte is specific to the microbes/microbial DNA, not an enzyme capable of passing through the second filter as taught by Doshi at Col. 15, lines 11-13. The result is a completely different method seeking to measure different things.

Therefore, the Applicants respectfully submit that even if one skilled in the art were to hypothetically combine Schrenk with Doshi, importing the lysing step of Schrenk into Doshi would still result in a process wherein the material that is analyzed in the methodology of the combined

Schrenk/Doshi disclosure would be different from the material analyzed in Claim 1. Therefore, the combination would lead one skilled in the art to a method different from the method recited in Claims 1-5, 8, 10, 14-16 and 23-28. Withdrawal of the rejection is respectfully requested.

Claims 6 and 7 stand rejected under 35 U.S.C. §103 over the further hypothetical combination of Cathey with Schrenk and Doshi. The Applicants respectfully submit that further hypothetically combining Cathey with the primary and secondary references does nothing to cure the deficiency set forth above with respect to the primary reference. Withdrawal of that rejection is also respectfully requested.

Claims 9 and 13 stand rejected under 35 U.S.C. §103 over the further hypothetical combination of Besson-Faure with Schrenk and Doshi. The Applicants respectfully submit that the further hypothetical combination of Besson-Faure with the primary and secondary references would fail to cure the deficiency set forth above with respect to the primary reference. Withdrawal of the rejection is respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,



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